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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,833	09/26/2003	Mark Edward Riehl	NNI-0005	1330

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EXAMINER	
HOPKINS, CHRISTINE D	
ART UNIT	**PAPER NUMBER**
3735	

NOTIFICATION DATE	DELIVERY MODE
07/05/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

eofficemonitor@woodcock.com

Office Action Summary	Application No.	Applicant(s)	
	10/672,833	RIEHL, MARK EDWARD	
	Examiner	Art Unit	
	CHRISTINE HOPKINS	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 April 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 7-69* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 7-69* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 25 April 2011 has been entered. Claims 1-5 and 7-69 are now pending. The Examiner acknowledges the amendments to claims 1, 44 and 67 as well as the cancellation of claim 6.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-5 and 7-69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding claims 1 and 67, it appears that the circuit pad comprises a conductor *and* a magnetic stimulation device. Based on the drawings of the instant specification (Figs. 5 and 6), the magnetic stimulation device appears to be separate from the circuit pad. Therefore, the circuit pad does not appear itself, to *comprise* a conductor *and* a magnetic stimulation device based upon the

drawings and according to the preamble. Nonetheless, the claim will be interpreted as recited. Furthermore, the recitation at line 7 of claims 1 and 67 of “an interface with the magnetic stimulation device” does not provide a positive recitation as an "interface” does not imply a structural relationship in as much as it appears imply an intended use for the connector.

Claim 26 at line 2 recites "magnetic flux density created by the magnetic stimulation device." This recitation renders the claim indefinite as claim 1, from which it depends, only recites a conductor which is adapted to reduce stimulation by a magnetic stimulation device” and does not positively claim a magnetic stimulation device. Claim 27 at line 2 recites "a magnetic field created by the magnetic stimulation device." This recitation renders the claim indefinite as claim 1, from which it depends, only recites a conductor which is adapted to reduce stimulation by a magnetic stimulation device” and does not positively claim a magnetic stimulation device. Claim 38 at line 2 recites "an electric field vector induced by the magnetic stimulation device." This recitation renders the claim indefinite as claim 1, from which it depends, only recites a conductor which is adapted to reduce stimulation by a magnetic stimulation device” and does not positively claim a magnetic stimulation device.

Claim 1 at line 6, claim 44 at line 7 and claim 67 at line 6 recite "wherein the connector provides an interface with the magnetic stimulation device". It is unclear what is meant by "interface" because the connector is connected to the conductors as recited in the claim, and at paragraph [0063] of the instant specification, but it remains

uncertain what is being claimed by an interface between the connector and the magnetic stimulation device in light of the specification.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-5, 7-21, 23, 24, 28-30 and 35-42 are rejected under 35 U.S.C. 102(e) as being anticipated by Fox et al. (U.S. Pub. No. 2003/0050527). Fox et al. (hereinafter Fox) disclose an apparatus and method for delivering transcranial magnetic stimulation. Regarding claims 1-5, 21, 23, 24, 36, 40-42 and 67-69, Fox teaches a circuit pad comprising a flat metallic conductor (copper windings) encased in plastic ("two surfaces of the circuit pad") and located proximate to a magnetic stimulator (Figs. 12 and 13) inducing a strong magnetic field at around 2 Tesla [0006]. Standard connections from the coil to cabling necessary to adapt the coil to a magnetic stimulator are present [0153]. The magnetic stimulation device is capable of reducing stimulation. A minimum inductance configuration may also be achieved for peripheral nerve stimulation ([0153]-[0154]). A predetermined location, such as a peripheral nerve portion, may be located prior to stimulation ([0028]-[0029]). Regarding claims 7-17, the "disposal mechanism" is

interpreted as the thermally conductive epoxy used to enhance heat dissipation [0153] because its removal would render the circuit pad inoperable since its purpose is to reduce stimulation on the brain induced by the stimulation device. The epoxy permits the patient to use the circuit pad for a certain period of time since it reduces heat received to the scalp of the patient while stimulation is conducted.

Regarding claims 18-19, the circuit pad would become inoperable and would also be capable of disintegrating if placed in contact with certain cleaning solutions. Regarding claim 20, the circuit pad is adapted to be attached to the patient since it is encased in non-conducting materials or a thermally conductive epoxy to enhance heat dissipation [0153].

Regarding claims 28-30, the conductors and stimulation device are both fully capable of being provided with electrical energy of opposite polarities substantially simultaneously [0079].

In view of claims 35, 38 and 39, a relatively longer dimension of the conductor, which also has a portion which is "arc-shaped," is placed along a similar direction as a electric field vector induced by a magnetic stimulation device (Fig. 1). Regarding claim 37, the conductor **10** has a high aspect ratio (Fig. 1).

Further regarding claims 67-69, the body portion of the stimulator may be made of air, ferrite or other materials [0079]. Standard connections from the coil to cabling necessary to adapt the coil to a magnetic stimulator are present [0153].

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fox et al. (U.S. Pub. No. 2003/0050527) in view of Mechlenburg et al. (U.S. Pub. No. 2001/0018547). Fox discloses the invention as claimed, see rejection supra; however Fox does not disclose expressly that the circuit pad comprises an adhesive. Mechlenburg et al. (hereinafter Mechlenburg) teaches a device and method for magnetic stimulation to treat various disorders. Regarding claim 22, Mechlenburg teaches a magnetic stimulation device **30** comprising a collar portion for wrapping around the neck of the patient and a coil for generating the magnetic field [0032]. The collar is attached to the patient using any suitable method, such as an adhesive [0072]. Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to have to have utilized an adhesive as taught by Mechlenburg, in order to secure a pad comprising a stimulation coil to a patient as taught by Fox, for ensuring that the proper treatment area is stimulated.

8. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fox et al. (U.S. Pub. No. 2003/0050527). Fox discloses the invention as claimed, see rejection supra; however Fox does not disclose expressly that the conductor of the circuit pad has an area in the range of 1 cm^2 to 40 cm^2. Instead, Fox indicates that the conductors may have a diameter between about 0.1 mm and 1.0 mm which will be placed on the

scalp of a patient ([0150]-[0153]). At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to construct a circuit pad having conductors with a an area in such dimensions provide an advantage, is used for a particular purpose, or solves a stated problem as opposed to any other which would be used on the scalp of a patient. One of ordinary skill in the art would have expected Fox's circuit pad and applicant's invention, to perform equally well with either the dimensions taught by Fox or the claimed flexible dimensions because both would perform the same function of enabling stimulation to the scalp of a patient. Therefore, at the time of the invention it would have been prima facie obvious to modify Fox to obtain the invention as specified in claim 25 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Fox.

9. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fox et al. (U.S. Pub. No. 2003/0050527) in view of Ishikawa et al. (U.S. Patent No. 5,984,854). Fox discloses the invention as claimed, see rejection supra; however Fox fails to disclose reducing stimulation by reducing a magnetic flux density created by the magnetic stimulation device. Ishikawa et al. (hereinafter Ishikawa) teaches that the stimulating coils producing a higher magnetic flux (1 Tesla) with selective stimulation, as likewise taught by Fox, may induce increasing heat in the tissue, resulting in pain or burning of the patient, necessitating some sort of cooling apparatus (col. 9, lines 3-28). Ishikawa further discloses reducing the stimulation pulses, thereby reducing the flux, leading to reduced pain (col. 5, lines 60-67 - col. 7, lines 1-12). Therefore, at the time of

the invention it would have been obvious to one having ordinary skill in the art to have reduced the magnetic flux density in focused stimulation as taught by Ishikawa, in a system for treating a specific area of a patient as suggested by Fox, as a reduction of magnetic flux would obviously reduce stimulation and pain to a treatment area.

10. Claims 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fox et al. (U.S. Pub. No. 2003/0050527) in view of Henley et al. (U.S. Patent No. 6,477,410). Fox discloses the invention as claimed, see rejection supra; however Fox fails to disclose a conductive gel facilitating communication between the circuit pad and a treatment area. Henley et al. (hereinafter Henley) disclose a device for self-administration of medicament to a treatment site. Regarding claims 31-33, Henley teaches a conductive gel that facilitates electrical conduction between a treatment area and an electrode **30** of an applicator. The conductive gel may be provided within a porous, or "absorbent" substrate **42** of pad **44**. The porous substrate **42** is interpreted as a sponge material (col. 20, lines 48-61). In view of claim 34, the substrate may also be made of a plastic material, and shaped according to an individual's anatomy. Fox, likewise, incorporates an assembly that considers the anatomy of a patient's skull for treatment. Therefore, at the time of the invention it would have been obvious to one having ordinary skill in the art to have introduced a conductive gel for delivering treatment to an individual as suggested by Henley, to a device for reducing pain for an ailment to the head as suggested by Fox, for providing increased contact between the device and the individual for effective treatment of the site of interest.

11. Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fox et al. (U.S. Pub. No. 2003/0050527) in view of Davey et al. (U.S. Pub. No. 6,500,110). Fox discloses the invention as claimed, see rejection supra; however Fox fails to disclose that the magnetic stimulation device comprises a core that saturates at 0.5 Tesla or greater. However, Fox teaches the delivery of transcranial magnetic stimulation with precise and focused delivery to the brain [0126]. A magnetic core with a higher field saturation, for instance 1.5 T or higher as taught by Davey, provides greater focus and an enhanced magnetic field (col. 8, lines 15-25). At the time of the invention it would have been obvious to one of ordinary skill in the art to have incorporated a magnetic core of a magnetic stimulation device for focused treatment as taught by Fox, with a material that saturates at 0.5 Tesla or higher as suggested by Davey, in order to enhance the magnetic field and provide greater focus on the area of treatment.

Allowable Subject Matter

12. Claim 27 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

13. Claims 44-66 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

Response to Arguments

14. Applicant's arguments filed 25 April 2011 with respect to the rejection of claims 1-43 and 67-69 under 35 U.S.C. 112, second paragraph have been fully considered and are moot in view of the new grounds of rejection under 35 U.S.C. 112, second paragraph presented above.

15. Applicant's arguments filed 25 April 2011 with respect to the rejection of claims 1-21, 23, 24, 26-30, 35-51, 53-63, and 66-69 under 35 U.S.C. 102(e) citing Fox et al. (U.S. Pub. No. 2003/0050527) have been fully considered and are not persuasive. Applicant contends that Fox fails to disclose a connector as claimed. However, this argument is not persuasive. At paragraph [0153] of Fox, it is disclosed that standard connections from the coil to cabling necessary to adapt the coil to a magnetic stimulator are present [0153]. In view of the foregoing, the rejection of claims 1-5, 7-21, 23, 24, 28-30 and 35-42 under 35 U.S.C. 102(e) citing Fox et al. (U.S. Pub. No. 2003/0050527) has been maintained.

16. Applicant's arguments filed 25 April 2011 with respect to the rejection of claims 22 and 63 under 35 U.S.C. 103(a) citing Fox et al. (U.S. Pub. No. 2003/0050527) in view of Mechlenburg et al. (U.S. Pub. No. 2001/0018547) have been fully considered and are not persuasive. Applicant's arguments are contingent upon those presented with regards to claim 1, which are addressed above. In view of the foregoing, the rejection of claim 22 under 35 U.S.C. 103(a) citing Fox et al. (U.S. Pub. No.

2003/0050527) in view of Mechlenburg et al. (U.S. Pub. No. 2001/0018547) has been maintained.

17. Applicant's arguments filed 25 April 2011 with respect to the rejection of claim 25 under 35 U.S.C. 103(a) citing Fox et al. (U.S. Pub. No. 2003/0050527) have been fully considered and are not persuasive. Applicant's arguments are contingent upon those presented with regards to claim 1, which are addressed above. In view of the foregoing, the rejection of claim 25 under 35 U.S.C. 103(a) citing Fox et al. (U.S. Pub. No. 2003/0050527) has been maintained.

18. Applicant's arguments filed 25 April 2011 with respect to the rejection of claims 31-34 under 35 U.S.C. 103(a) citing Fox et al. (U.S. Pub. No. 2003/0050527) in view of Henley et al. (U.S. Patent No. 6,477,410) have been fully considered and are not persuasive. Applicant's arguments are contingent upon those presented with regards to claim 1, which are addressed above. In view of the foregoing, the rejection of claims 31-34 under 35 U.S.C. 103(a) citing Fox et al. (U.S. Pub. No. 2003/0050527) in view of Henley et al. (U.S. Patent No. 6,477,410) has been maintained.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTINE HOPKINS whose telephone number is

(571)272-9058. The examiner can normally be reached on Monday-Friday, 7 a.m.-3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. D. H./
Christine D Hopkins
Examiner
Art Unit 3735